UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DOLISKA HANRAHAN and ROBERT HANRAHAN,	)	
Plaintiffs,	)	
vs.	)	Case No. 4:04CV01255 ERW
WYETH, INC. et al.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter comes before the Court upon Defendants' Motion to Exclude Testimony of Experts Drs. Michael Maloney and Raymond Hartman [ECF No. 58], Defendants' Motion to Exclude Testimony of Plaintiff's Expert's Dr. Matthew Hollon, Dr. Adriane Fugh-Berman and Dr. Warren Keegan [ECF No. 62], and Defendants' Motion to Exclude Expert Testimony that OMP is a Safer Alternative than MPA [ECF No. 64].

Legal Standard for Admissibility of Expert Testimony

Rule 702 mandates a policy of liberal admissibility, and expert testimony is permitted if it will assist the trier of fact in understanding the evidence or to determine a fact in issue. Fed. R. Evid. 702; *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). To be admitted under Rule 702, proposed expert testimony must meet three prerequisites: 1) any evidence based on scientific, technical or other specialized knowledge must be useful to the fact finder in determining a fact in issue; 2) the proposed witness must be qualified to assist the fact finder; and 3) the proposed evidence must be reliable or trustworthy in an evidentiary sense. *Id.; Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590-93 (1993).

A district court's goal in assessing expert testimony is to ensure that "all scientific testimony is both reliable and relevant." *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010) (quoting *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006)). The reliability requirement means that "the party offering the expert testimony must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid," while the relevance requirement demands "the proponent must show that the expert's reasoning or methodology was applied properly to the facts at issue." *Id.* (internal quotations and citations omitted).

Rule 702's requirements notwithstanding, "[c]ourts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Marmo*, 457 F.3d at 758. This is because the Rule "only requires that an expert possess 'knowledge, skill, experience, training, or education' sufficient to 'assist' the trier of fact, which is 'satisfied where expert testimony advances the trier of fact's understanding to any degree.'" *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (internal citation omitted). As such, "[g]aps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility." *Id.* at 1100-01.

I. Defendants' Motion to Exclude Testimony of Plaintiff's Experts Dr. Michael Maloney and Raymond Hartman [ECF No. 58]

In this Motion, Defendants move to exclude testimony by Drs. Michael Maloney and Raymond Hartman, which purports to estimate a range of punitive damages that should be awarded. Defendants do not challenge the qualifications of these experts; rather, Defendants claim that the proposed testimony of these two experts is irrelevant and misleading under Federal Rules of Civil Procedure 402 and 403, and that their opinions constitute improper expert testimony under Rule 702.

According to Defendants, Drs. Maloney's and Hartman's proposed testimony regarding the appropriate range of punitive damages invades the province of the jury, and is based on an unreliable methodology. They further aver that the reports of these experts, proffering opinions regarding the financial importance of Hormone Replacement Therapy (HRT) medications to Defendants and Defendants' ability to pay for studies of these medications, are based on stale sales data; thus, Defendants maintain the reports have no relevance to this action. Defendants claim that much of the experts' proposed testimony consists of reciting from documents, or repeating undisputed facts, and thus is cumulative and not helpful to the jury. Additionally, Defendants assert that the opinions concerning Defendants' net worth are irrelevant, are based on unreliable methodology, and would confuse and mislead the jury.

In her Response, Plaintiff states that she does not intend to have Dr. Maloney testify to an appropriate range of punitive damages, and that she will call Dr. Maloney "solely to testify as to Wyeth's and Pfizer's net worth during a punitive phase of the trial." (*See Plaintiff's Response in Opposition to Defendants' Motion to Exclude Testimony of Plaintiff's Experts Drs. Michael Maloney and Raymond S. Hartman*, p. 1). As noted by Plaintiff in her Response and acknowledged by Defendants in their Reply, this qualification moots much of Defendants' argument concerning Dr. Maloney, leaving only their objections to his testimony regarding Defendants' net worth[1]. Consequently, although the remainder of the discussion regarding Defendants' Motion to Exclude Testimony of Plaintiff's Experts Drs. Michael Maloney and

[1]In their Reply [ECF No. 83], Defendants state: "Taking Plaintiff at her word leads to an easy conclusion of this motion[;] . . . Wyeth is willing to stipulate to its net worth in the event punitive damages are at issue, thereby obviating the need for Dr. Maloney to testify at trial." (*Defendants' Reply in Support of their Motion to Exclude Testimony of Plaintiff's Experts Drs. Michael Maloney and Raymond Hartman*, p. 1).

Raymond S. Hartman shall pertain only to Dr. Hartman, the Court will first address Defendants' objection to the net worth testimony of these both experts.

In their challenge to Dr. Maloney's and Dr. Hartman's net worth testimony, Defendants argue that the experts' method of estimating Wyeth's net worth is a market capitalization calculation that is "not tied to, and does not provide any evidence of, Wyeth's net worth." They further assert that the testimony will serve only to confuse and mislead the jury, claiming that "market capitalization is not a reliable method of calculating net worth, does not comply with Dr. Maloney's own definition of net worth, and does not satisfy the *Daubert* standard." Plaintiffs' experts have supplied an analysis of the economic principles used in determining their net worth calculations. According to Dr. Hartman, market capitalization provides an "upper bound" in determining a firm's ability to pay any punitive damage award, and is the most readily available measure of its market value.

Defendants' challenge here attacks the evidence's weight, rather than its admissibility; thus, the probative value of the expert's testimony is a matter for the trier of fact to resolve, and any weakness in the evidence may be more appropriately exposed by cross-examination or presentation of contrary evidence.

In addition to their argument attacking the reliability of experts' methodology and testimony, Defendants claim that net worth testimony: 1) is irrelevant to a punitive damages determination; 2) is improper for a jury to consider in awarding punitive damages; 3) is constitutionally forbidden because Wyeth's net worth is overwhelmingly derived from conduct that is not challenged as wrongful and that is entirely unrelated to Plaintiff; 4) impermissibly appeals to bias against large out-of-state corporations; and 5) impermissibly punishes a company for its size while not serving the deterrence rationale for punitive damages.

Notwithstanding Defendants' contentions, the Supreme Court has recognized the relevance and usefulness of net worth evidence in a jury's consideration of a punitive damage award. "Under well-settled law, however, factors such as [evidence of corporation's impressive net worth] are typically considered in assessing punitive damages." *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 462 n. 28 (1993). Plaintiff's experts will be permitted to testify concerning Wyeth's net worth during a punitive damages phase of the trial.

As to Defendants' remaining objections to Dr. Hartman, they assert that his testimony is not based on any reliable or accepted methodology, and claim that his testimony regarding the economic importance of the Premarin drug product line to Wyeth "is based entirely on inferences drawn from reviewing historical sales data, Wyeth's public reports, Wyeth's educational efforts, and other 'readily available documentation.'" Accordingly, Defendants argue his testimony would not aid jurors, as they are capable of reading the documents, and drawing the inferences for themselves.

Dr. Hartman is an economist specializing in microeconomics, econometrics, and the study of industrial organizations [ECF No. 79-5]. Econometrics is a science that makes use of mathematics and statistics to measure and quantify economic behavior and economic phenomena in markets. A review of Dr. Hartman's expert report reveals that he conducted extensive research on Wyeth's financial status over the span of over sixty years, reviewed voluminous public and internal documents, and applied widely accepted methods of economic analysis in preparing his expert opinion.

Defendants' argument that Dr. Hartman's testimony would not be helpful to jurors because they are capable of reading the documents and drawing inferences without such assistance is clearly refuted with a cursory reading of his report. The report contains analyses of

information contained in the numerous documents considered by Dr. Hartman that would serve to advance the jury's understanding the profitability of the Premarin family of products and their contribution to Wyeth's financial status. Among other things, Dr. Hartman explains a change in the form of Wyeth's financial reporting disclosures that occurred in 2002. According to Dr. Hartman, the company's annual reports disclosed information regarding Premarin's contribution to profit in terms of sales and operating income between the years of 1997 and 2001. Dr. Hartman used this information to calculate ratios for Premarin-related net income and sales as compared to Wyeth's consolidated net income and sales. However, Dr. Hartman reported that, beginning in 2002, Wyeth's annual reports disclosed information regarding Premarin's contribution as net revenue and gross profits generated by the drug products. Consequently, Dr. Hartman's analyses regarding Premarin's contribution utilized gross profit measures relative to net revenue to derive the measure of marginal profit. This type of explanatory testimony satisfies Rule 702's requirement that the expert testimony advances the trier of fact's understanding.

Dr. Hartman's testimony is both reliable and relevant. *Barrett*, 606 F.3d at 980. Again, Defendants' arguments for exclusion go to the weight, not admissibility, of this expert's testimony. Raising questions about, and exposing gaps in, Dr. Hartman's analyses and conclusions is a task for Defendants to perform in front of a jury.

Accordingly, the Court finds that the testimony of Dr. Maloney and Dr. Hartmann as to the Defendants' net worth is admissible during a punitive damages phase of the trial. The Court further finds that the testimony of Dr. Hartmann regarding the economic importance of the Premarin drug product line to Wyeth is admissible during a punitive damages phase of the trial. Defendants' Motion to Exclude Testimony of Plaintiff's Experts Dr. Michael Maloney and Raymond Hartman [ECF No. 58] will be denied.

II. Defendants' Motion to Exclude Testimony of Plaintiff's Experts Dr. Matthew Hollon, Dr. Adriane Fugh-Berman and Dr. Warren Keegan [ECF No. 62].

In this Motion, Defendants move to exclude testimony of Plaintiff's experts Dr. Matthew Hollon, Dr. Adriane Fugh-Berman, and Dr. Warren Keegan regarding drug marketing practices. Defendants claim that the testimony of these experts is irrelevant because Plaintiff has no evidence showing that she, or her prescribing health care providers, relied on any inaccurate marketing materials, nor evidence indicating that those materials, or any conduct involving Defendants' advertising or marketing, caused her injuries. Defendants further argue that the experts' narrative history will not assist the jury, and that the proposed testimony is not based on sufficient data or a reliable scientific methodology. Additionally, Defendants assert that Dr. Hollon improperly speculates about Wyeth's intent, motive, knowledge, and state of mind; and that his testimony regarding the standard of care for pharmaceutical marketing is inadmissible because it is not based on the legal standard contained in federal pharmaceutical regulations.

Defendants do not challenge the qualification of these experts, and, indeed, the record shows that all three experts have a knowledge of pharmaceutical marketing that exceeds a juror's common understanding. Dr. Hollon is a board-certified physician specializing in internal medicine, with a Masters of Public Health; formerly, he was the Director of Evidence-Based Medicine for the Internal Medicine Residency Program at the University of Washington's Department of Medicine. He has authored published reviews and editorials on the effects of pharmaceutical marketing and its effects.

Dr. Fugh-Berman is licensed to practice medicine and surgery, and she an associate professor in the department of physiology and biophysics at Georgetown University Medical Center, where, among other things, she lectures graduate and medical students regarding

pharmaceutical company influence on physician prescribing practices. Dr. Fugh-Berman is a co-author of *The Truth about Hormone Therapy*.

Dr. Keegan is a Fellow of the Academy of International Business and he holds a Doctor of Business Administration from Harvard University. As well, he is a Distinguished Professor of Marketing and International Business at Pace University and a former officer of the American Marketing Association, in which he remains active in national program planning.

In her Response to Defendants' Motion, Plaintiff argues that the proffered expert testimony regarding the manner in which Defendants conveyed risk and benefit information through their HRT marketing and promotion efforts is crucial to the jury's determination as to whether Defendants failed their duty adequately to warn the medical community and consumers. In his testimony, Dr. Hollon opines that Defendants irresponsibly failed to meet a reasonable standard of care in promoting their HRT drugs, stimulating inappropriate prescribing, and that there was substantial harm as a result of over-treatment. Dr. Fugh-Berman also opines that Defendants' conduct fell beneath accepted standards of practice, resulting in harm. Dr. Keegan opines that Defendants' marketing campaign promoted long-term treatment of short-term symptoms of a life event, resulting in a wide expansion of the HRT market, and contributed to off-label use.

Plaintiff also claims that Defendants' marketing plan impacted her prescribing physicians' beliefs about HRT's benefits, contributing to their belief that HRT provided cardiovascular benefit and protected against Alzheimer's Disease. In depositions, Plaintiff's prescribing physicians variously testified that, prior to the *Journal of the American Medical Association's* publication of findings in a study by the Women's Health Initiative (WHI) in July 2002, they believed that HRT provided a heart, bone and brain benefit. One of Plaintiff's

gynecologists, John K. Appelbaum, MD, additionally stated that prior to the WHI study, the medical community believed it was acceptable to continue women on HRT for long-term use.

The Court finds that evidence of the manner in which Defendants conveyed HRT risk and benefit information through their marketing and promotion efforts is admissible and relevant in assisting the jury's consideration of the character of the defendants' acts and their influence on HRT prescribing practices. Again, Defendants' challenges to the bases for these experts' opinions are issues for cross-examination. *Barrett*, 606 F.3d at 980. Defendants' Motion to Exclude Testimony of Experts Dr. Matthew Hollon, Dr. Adriane Fugh-Berman and Dr. Warren Keegan [ECF No. 62] will be denied.

III. Defendants' Motion to Exclude Expert Testimony that OMP is a Safer Alternative than MPA [ECF No. 64]

In this Motion, Defendants move the Court to exclude the opinions of Plaintiff's experts, particularly that of Dr. Donald Austin, which state that Premarin combined with micronized progesterone ("OMP") is a safer alternative to Premarin combined with medroxyprogesterone acetate ("MPA"). Defendants argue that testimony regarding this opinion is inadmissible because Plaintiff has failed to meet her burden of proof regarding the design defect claim contained in the Complaint she filed against Defendants, making such testimony irrelevant. However, in a Memorandum and Order issued this date, this Court considered Defendants' argument that Plaintiff's design defect claims should be dismissed as a matter of law because she cannot prove a defect specific to the design of Defendants' HRT drugs. This Court denied Defendants' request for summary judgment on this issue, finding that Plaintiff has offered sufficient evidence to support a finding that the HRT drugs were in a defective condition unreasonably dangerous when they were prescribed for Plaintiff. Consequently, the proffered expert testimony is relevant.

Defendants further aver that the testimony should be excluded because it is unreliable. The majority of Defendants' argument challenges the relevance and reliability of Dr. Austin's report, but Defendants also discuss testimony by Dr. Peter H. Gann. Interestingly, in a position seemingly inconsistent with their Motion to Exclude, Defendants claim that this expert has conceded that combining Premarin with OMP is not a safer alternative design to Premarin combined with MPA and they urge this Court to "give particular weight to Dr. Gann's opinion[.]" In support of their Motion, Defendants direct this Court's attention to two orders granting their motions to exclude testimony that OMP is a safer alternative to MPA, that were issued by district courts in West Virginia and Texas. *See Hines v. Wyeth, et al.*, No. 2:04-0690, 2011 WL 2680814 (S.D. W.Va. July 8, 2011); *Lea v. Wyeth LLC, et al.*, No. 1:03-001339 (E.D. Tex. Sept. 16, 2011).

In her Response opposing Defendants' Motion to Exclude Expert Testimony that OMP is a Safer Alternative than MPA, Plaintiff states that the report ruled upon by these two district courts in 2011 is not the most recent report authored by proffered expert Dr. Austin. Plaintiff has submitted a copy of Dr. Austin's Supplemental Expert Report. This report, authored in September 2011, directly responds to the West Virginia and Texas federal court rulings that excluded his testimony, addressing the points raised in their analyses.

In addition to recognizing that the 2011 rulings concerned an earlier report lacking this supplemental explanation, this Court notes that the prior rulings considered reports by Dr. Austin and a different expert, Dr. Wayne Tilley; the analyses did not address Dr. Gann's testimony. *See Hines*, 2011 WL 2680814 (excluding the expert opinion of Drs. Wayne Tilley and Donald Austin that OMP is a safer alternative to MPA upon finding that the studies upon which the experts relied did not provide a reliable basis for the proffered testimony); *Lea*, No. 1:03-001339 (also

excluding the expert opinion of Drs. Tilley and Austin, after finding that the studies upon which the experts relied did not provide a reliable basis for the proffered testimony). Accordingly, the determinations made by the West Virginia and Texas courts are distinguishable, as they considered expert testimony substantially different from that proffered here.

Defendants' Motion seeks to exclude all expert testimony that OMP is a safer alternative to MPA generally, on the grounds Dr. Austin's qualifications were not challenged in these prior rulings. As noted, the decisions to exclude Drs. Tilley's and Austin's opinions that OMP is a safer alternative to MPA were based on findings that the studies relied upon by these experts did not provide a reliable basis for their testimony. Defendants acknowledge, in a footnote to their Motion, that the HRT multidistrict litigation (MDL) court, from which this case was transferred, more recently denied their motion to exclude the very same testimony of Dr. Austin and Dr. Gann now proffered by Plaintiff in this case. *See In Re Prempro Prod. Liability Litig.*, No. 4:03-1507 (E.D. Ark. April 19, 2012) (denying Defendants' Motion to Bar Testimony of Drs. Austin, Gann, and Tilley Re: Design Defect). In its discussion, the MDL Court opined that, "[a]fter reading the 200+ pages of briefing from the parties, it appears to me that the parties are making summary judgment arguments, rather than *Daubert* arguments, since most of the discussion is centered around the merits of Plaintiffs' design defect claim." *Id. at 4.* As to the actual *Daubert* issues raised by Defendants, the MDL Court found that they were objections to the adequacies of the studies used by the experts to support their opinions, and held that such objections went to the weight, rather than the admissibility, of the expert evidence. *Id.* In the words of the MDL Court, "There is no analytical leap in the experts' opinions that would warrant the exclusion of their testimony. The experts state that OMP has a lower risk of breast cancer than MPA, and they provided studies to support their opinions." *Id.*

This Court likewise finds that Defendants' argument attacks the credibility of the expressed opinion that OMP is a safer alternative to MPA, and that it does so by challenging the adequacy of the studies provided to support Dr. Austin's opinion, and by claiming that Dr. Gann has conceded that Premarin and OMP was not a safer alternative design. The evidence proffered by Plaintiff shows that these experts are providing scientific testimony that is the product of reliable principles and methods. The gaps or inadequacies identified by Defendants go to the evidence's weight, not admissibility. *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d at 1100-01. As such, Defendants can challenge the experts' interpretations of the studies' findings and point out any inconsistencies in testimony before a jury. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. Defendants' Motion to Exclude Expert Testimony that OMP is a Safer Alternative than MPA [ECF No. 64] will be denied.

Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion to Exclude Testimony of Experts Drs. Michael Maloney and Raymond Hartman [ECF No. 58], Defendants' Motion to Exclude Testimony of Plaintiff's Expert's Dr. Matthew Hollon, Dr. Adriane Fugh-Berman and Dr. Warren Keegan [ECF No. 62], and Defendants' Motion to Exclude Expert Testimony that OMP is a Safer Alternative than MPA [ECF No. 64] are **DENIED**.

Dated this 25th day of June, 2012.

E. RICHARD WEBBER
SENIOR UNITED STATES DISTRICT JUDGE